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Practitioner's Docket No.

2960/118

Application No.: 10/752,438  
Supplemental Information Disclosure Statement  
**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re application of: Fitz et al.

Application No.: 10/752,438

Group No.: 3738

Filed: January 5, 2004

For: Patient Selectable Joint Knee Arthroplasty Devices

**Mail Stop Amendment**

**Commissioner for Patents**

**P.O. Box 1450**

**Alexandria, VA 22313-1450**

**TRANSMITTAL OF SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT  
WITHIN THREE MONTHS OF FILING OR  
BEFORE MAILING OF FIRST OFFICE ACTION (37 C.F.R. § 1.97(b))**

**IDENTIFICATION OF TIME OF FILING THE ACCOMPANYING  
SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

The information disclosure statement submitted herewith is being filed within three months of the filing date of the application or date of entry into the national stage of an international application or before the mailing date of a first Office action on the merits, whichever event occurs last. 37 C.F.R. § 1.97(b).

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**CERTIFICATION UNDER 37 C.F.R. §§ 1.8(a) and 1.10\***

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**37 C.F.R. § 1.8(a)**

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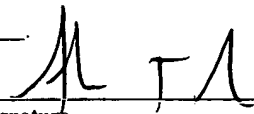
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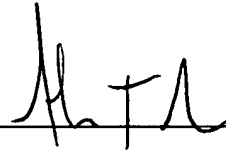
  
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Date: June 24, 2005

Alexander J. Smolenski, Jr., Esq.  
(type or print name of person certifying)

\* Only the date of filing (§ 1.6) will be the date used in a patent term adjustment calculation, although the date on any certificate of mailing or transmission under § 1.8 continues to be taken into account in determining timeliness. See § 1.703(f). Consider "Express Mail Post Office to Addressee" (§ 1.10) or facsimile transmission (§ 1.6(d)) for the reply to be accorded the earliest possible filing date for patent term adjustment calculations.

DATE: June 24, 2005



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2960/118 395767

Practitioner's Docket No. 2960/118

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Patent application

of \_\_\_\_\_

Inventor(s)

for \_\_\_\_\_

Title of invention

the specification of which is being transmitted herewith

OR

In re application of: Fitz et al.

Application No.: 10/752.438

Group No.: 3738

Filed: January 5, 2004

Examiner: Not yet assigned

For: **Patient Selectable Joint Knee Arthroplasty Devices**

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

**SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT**

(Information Disclosure Statement--page 1 of 15)

**CERTIFICATION UNDER 37 C.F.R. SECTIONS 1.8(a) and 1.10\***

(When using Express Mail, the Express Mail label number is *mandatory*;  
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I hereby certify that, on the date shown below, this correspondence is being:

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**37 C.F.R. SECTION 1.10\***

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Date: June 24, 2005

Signature



Alexander J. Smolenski, Jr., Esq.

**\*WARNING:** Each paper or fee filed by "Express Mail" must have the number of the "Express Mail" mailing label placed thereon prior to mailing. 37 C.F.R. section 1.10(b).

"Since the filing of correspondence under section 1.10 without the Express Mail mailing label thereon is an oversight that can be avoided by the exercise of reasonable C.F.R.e. requests for waiver of this requirement will not be granted on petition." Notice of Oct. 24, 1996, 60 Fed. Reg. 56,439, at 56,442.

**NOTE:** "An information disclosure statement shall be considered by the Office if filed by the applicant:

- (1) Within three months of the filing date of a national application;
- (2) Within three months of the date of entry of the national stage as set forth in section 1.491 in an international application; or
- (3) Before the mailing date of a first Office action on the merits, whichever event occurs last." 37 C.F.R. section 1.97(b).

**NOTE:** "Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section." 37 C.F.R. section 1.56(a).

"Individuals associated with the filing or prosecution of a patent application within the meaning of this section are:

- (1) each inventor named in the application;
- (2) each attorney or agent who prepares or prosecutes the application; and
- (3) every other person who is substantively involved in the preparation or prosecution of the application and who is associated with the inventor, with the assignee or with anyone to whom there is an obligation to assign the application." 37 C.F.R. section 1.56(c).

**NOTE:** The "duty as described in section 1.56 will be met so long as the information in question was cited by the Office or submitted to the Office in the manner prescribed by sections 1.97(b) - (d) and 1.98 before issuance of the patent." Notice of January 9, 1992, 1135 O.G. 13-25 at 17.

**WARNING:** "No information disclosure statement may be filed in a provisional application." 37 C.F.R. section 1.51(b).

### **List of Sections Forming Part of This Supplemental Information Disclosure Statement**

The following sections are being submitted for this Information Disclosure Statement:

(check sections forming a part of this statement: discard unused sections and number pages consecutively)

1. ☒ Preliminary Statements
2. ☒ Forms PTO/SB/08A and 08B (substitute for Form PTO-1449)
3. ☐ Statement as to Information Not Found in Patents or Publications
4. ☐ Identification of Prior Application in Which Listed Information Was Already Cited and for Which No Copies Are Submitted or Need Be Submitted
5. ☐ Cumulative Patents or Publications
6. ☒ Copies of Listed Information Items Accompanying This Statement
7. ☐ Concise Explanation of Non-English Language Listed Information Items
  - 7A. ☒ EPO Search Report
  - 7B. ☐ English Language Version of EPO Search Report
8. ☐ Translation(s) of Non-English Language Documents
9. ☐ Concise Explanation of English Language Listed Information Items (Optional)
10. ☒ Identification of Person(s) Making This Information Disclosure Statement

(complete the following, if appropriate)

Sections \_\_\_\_\_, respectively, have been continued on ADDED PAGE(S).

**NOTE:** "Once the minimum requirements are met, the examiner has an obligation to consider the information." Notice of April 20, 1992 (1138 O.G. 37-41, 37).

**Section 1. Preliminary statements**

Applicants submit herewith patents, publications or other information, of which they are aware that they believe may be material to the examination of this application, and in respect of which, there may be a duty to disclose.

The filing of this information disclosure statement shall not be construed as a representation that a search has been made (37 C.F.R. section 1.97(g)), an admission that the information cited is, or is considered to be, material to patentability, or that no other material information exists.

The filing of this information disclosure statement shall not be construed as an admission against interest in any manner. Notice of January 9, 1992, 1135 O.G. 13-25, at 25.



Application No.: 10/752,438  
Supplemental Information Disclosure Statement  
**SECTION 2. FORMS PTO/SB/08A and 08B (formerly Form PTO-1449)**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Applicants: Fitz et al. Attorney Docket: 2960/118  
Appl. No: 10/752,438 Art Group Unit: 3738  
Date Filed: January 5, 2004 Examiner Name: Not yet assigned  
Invention: Patient Selectable Joint Knee Arthroplasty Devices

**LIST OF PATENTS AND PUBLICATIONS FOR  
APPLICANT'S INFORMATION DISCLOSURE STATEMENT**

U.S. PATENT DOCUMENTS					
Examiner Initials	Reference Number	Document Number	Issue Date/ Publication Date	Inventor	Class/Subclass
	AA	US 4,203,444	Apr. 1980	Bonnell et al.	128/176
	AB	US 4,586,496	May 1986	Keller	128/926
	AC	US 4,601,290	Jul. 1986	Effron et al.	128/305
	AD	US 5,671,741	Sep. 1997	Lang et al.	128/653.2
	AE	US 5,827,289	Oct. 1998	Reiley et al.	606/86
	AF	US 6,219,571	Apr. 2001	Hargreaves et al.	600/410
	AG	US 6,328,765	Dec. 2001	Hardwick et al.	623/23.72
	AH	US 6,352,558	Mar. 2002	Spector M.	623/18.11
	AI	US 6,358,253	Mar. 2002	Torrie et al.	606/96
	AJ	US 6,375,658	Apr. 2002	Hangody et al.	623/20.18
	AK	US 6,443,988	Sep. 2002	Felt et al.	623/17.12
	AL	US 6,479,996	Nov. 2002	Hoogeveen et al.	324/309
	AM	US 6,520,964	Feb. 2003	Tallarida et al.	606/71
	AN	US 6,632,235	Oct. 2003	Weikel et al.	606/192
	AO	US 6,652,587	Nov. 2003	Felt et al.	623/20.16
	AP	US 6,679,917	Jan. 2004	Ek	600/587

U.S. Published Applications					
Examiner Initials	Ref. No.	Document Number	Issue Date/ Publication Date	Inventor	Class/Subclass
	AQ	US 2002/0059049	May 2002	Bradbury et al.	703/111
	AR	US 2002/0087274	Jul. 2002	Alexander et al.	702/19
	AS	US 2002/0183850	Dec. 2002	Felt et al.	
	AT	US 2003/0216669	Nov. 2003	Lang et al.	600/587
	AU	US 2005/0043807	Feb. 2005	Wood	623/20.14

FOREIGN PATENT DOCUMENTS						
Examiner Initials	Reference Number	Country Code	Document Number	Publication Date	Patentee or Applicant	Class/Subclass
	AV	EP	0 626 156	Jan. 1992	Walker, P.S.	A61F 2/38
	AW	WO	93/25157	Dec. 1993	Rau et al.	A61B 17/57
	AX	WO	00/59411	Oct. 2000	Fell et al.	A61F 2/38
	AY	WO	01/19254	Mar. 2001	Cummings et al.	A61B 17/00
	AZ	WO	01/70142	Sep. 2001	Carigan et al.	A61F 2/38
	BA	WO	02/22014	Mar. 2002	Alexander et al.	A61B 5/055
	BB	WO	02/23483	Mar. 2002	Steines et al.	G06T 11/0
	BC	WO	02/34310	May 2002	Dickson et al.	A61L 31/04
	BD	WO	02/06268	Dec. 2002	Lang et al.	A61F
	BE	WO	03/007788	Jan. 2003	Prasanna et al.	A61F
	BF	WO	03/051210	Jun. 2003	Ek et al.	A61B 17/58
	BG	WO	04/043305	May 2004	Tsougarakis et al.	A61F 2/30

OTHER DOCUMENTS			
Examiner Initials	Reference Number	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
	BH	Lam et al.	X-Ray Diagnosis: A Physician's Approach, ISBN 981-2083-24-7, Index
	BI	Tamez-Pena, J. et al.	"MRI ISOTROPIC RESOLUTION RECONSTRUCTION FROM TWO ORTHOGONAL SCANS", Proceedings of the SPIE-The International Society for Optical Engineering SPIE-OMT. Vol. 4322, pp. 87-97, 2001.
	BJ	Taha et al.	"Modeling and design of a custom made cranium implant for large skull reconstruction before a tumor removal", Phidias Newsletter No. 6, pgs 3-6, June 2001. Retrieved from the Internet: URL: <a href="http://www.materialise.com/medical/files/pdf">http://www.materialise.com/medical/files/pdf</a>

OTHER DOCUMENTS

Examiner Initials	Reference Number	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
	BK	Kidder, J. et al.	"3D model acquisition design, planning and manufacturing of orthopaedic devices: a framework", Proceedings of the SPIE-Advanced Sensor and Control-System Interface, Boston, MA, Vol. 2911, pgs. 9-22, 21 November 1996.
	BL	Carr, J.C. et al.	"Surface Interpolation with Radial Basis Functions for Medical Imaging", IEEE Transactions on Medical Imaging, IEEE, Inc. New York, Vol. 16, No. 1, 1 February 1997, pgs. 96-107.
	BM	Ranawat, C.S. et al.	"MacIntosh Hemiarthroplasty in Rheumatoid Knee", Acta Orthop Belg. 1973 Jan-Feb: 39 (1): pgs. 102-112.
	BN	Blum, B. et al.	"Knee Arthroplasty in Patients with Rheumatoid Arthritis", ANN. Rheum. Dis. 1974 Jan: 33 (1): pgs. 1-11.
	BO	Nelson M.D., et al.	"Arthroplasty and Arthrodesis of the Knee Joint", Orthop. Clin. North Am. 1971 Mar: 2 (1): pgs. 245-264.
	BP	McCollum, et al.	"Tibial Plateau Prosthesis in Arthroplasty of the Knee", J. Bone Joint Surg. Am. 1970 Jun: 52 (4): pgs. 827-828.
	BQ	Hastings, D.E. et al.	"Double Hemiarthroplasty of the Knee in Rheumatoid Arthritis. A Survey of Fifty Consecutive Cases", J. Bone Joint Surg. Br. 1973 Feb: 55 (1): pgs. 112-118.
	BR	Schron, D. et al.	"MacIntosh Arthroplasty in Rheumatoid Arthritis", Rheumatol Rehabil. 1978 Aug: 17 (3): pgs. 155-163.
	BS	McKeever, D.C. et al.	"The Classic Tibial Plateau Prosthesis", Clin. Orthop. Relat. Res. 1985 Jan-Feb: (192): pgs. 3-12.
	BT	Conaty et al.	"Surgery of the Hip and Knee in Patients with Rheumatoid Arthritis", J. Bone Joint Surg. Am. 1973 Mar: 55 (2): pgs. 301-314.



Application No.: 10/752,438

Supplemental Information Disclosure Statement

**OTHER DOCUMENTS**

<b>Examiner Initials</b>	<b>Reference Number</b>	<b>Author</b>	<b>Title of Article, Title of Journal, Volume Number, Page Numbers, Date</b>
	<b>BU</b>	<b>MacIntosh et al.</b>	<b>"The Use of the Hemiarthroplasty Prosthesis for Advanced Osteoarthritis and Rheumatoid Arthritis of the Knee", J. of Bone &amp; Joint Surg. 1972, Vol. 54B, No. 2, pgs. 244-255.</b>
	<b>BV</b>	<b>MacIntosh, D.L.</b>	<b>"Arthroplasty of the Knee in Rheumatoid Arthritis Using the Hemiarthroplasty Prosthesis", Synovectomy and Arthroplasty in Rheumatoid Arthritis, pp. 79-80, Second Int'l. symposium, Jan. 27-29, 1967 (Basle, Switzerland).</b>
	<b>BW</b>	<b>Stauffer, R. et al.</b>	<b>"The MacIntosh prosthesis. Prospective Clinical and Gait Evaluation", Arch. Surg. 1975 Jun: 110 (6): pgs. 717-720.</b>
	<b>BX</b>	<b>Clary, B.B. et al.</b>	<b>"Experience with the MacIntosh Knee Prosthesis", South Med. J. 1972 Mar: 65 (3): pgs. 265-272.</b>
	<b>BY</b>	<b>Ghelman, M.D. et al.</b>	<b>"Kinematics of the Knee After Prosthetic Replacements", Clin. Orthop. 1975 May: (108): pgs. 149-157.</b>
	<b>BZ</b>	<b>Henderson, M.D. et al.</b>	<b>"Experience with the Use of the MacIntosh Prosthesis in Knees of Patients with Rheumatoid Arthritis", South. Med. J. 1969 Nov: 62 (11): pgs. 1311-1315.</b>
	<b>CA</b>	<b>Potter, M.D.</b>	<b>"Arthroplasty of the Knee With Tibial Metallis Implants of the McKeever and MacIntosh Design", Surg. Clin. North Am. 1969 Aug: 49 (4): pgs. 903-915.</b>
	<b>CB</b>	<b>Potter, T.A. et al.</b>	<b>"Arthroplasty of the Knee in Rheumatoid Arthritis and Osteoarthritis: A Follow-up Study After Implantation of the McKeever and MacIntosh Prostheses", J. Bone Joint Surg. Am. 1972 Jan: 54 (1): pgs. 1-24.</b>
	<b>CC</b>	<b>Bogoch et al.</b>	<b>"Supracondylar Fractures of the Femur Adjacent to Resurfacing and MacIntosh Arthroplasties of the Knee in Patients with Rheumatoid Arthritis", Clin. Orthop. 1988 Apr. (229): pgs. 213-220.</b>

**OTHER DOCUMENTS**

Examiner Initials	Reference Number	Author	Title of Article, Title of Journal, Volume Number, Page Numbers, Date
	CD	Cameron et al.	"Review of a Failed Knee Replacement and Some Observations on the Design of a Knee Resurfacing Prosthesis", Arch. Orthop. Trauma Surg. 1980: 97 (2): pgs. 87-89.
	CE	Kates, A. et al.	"Experiences of Arthroplasty of the Rheumatoid Knee Using MacIntosh Prostheses", Ann. Rheum. Dis. 1969 May: 28 (3): pg. 328.
	CF	Jessop, J.D. et al.	"Follow-up of the MacIntosh Arthroplasty of the Knee Joint", Rheumatol Phys. Med. 1972 Feb: 11 (5): pgs. 217-224.
	CG	Andersson, G.B. et al.	"MacIntosh Arthroplasty In Rheumatoid Arthritis", Acta. Orthop. Scand. 1974: 45 (2): pgs. 245-259.
	CH	Wordsworth et al.	"MacIntosh Arthroplasty for the Rheumatoid Knee: A 10-year Follow Up", Ann. Rheum. Dis. 1985 Nov: 44 (11): pgs. 738-741.
	CI	Kay, N.R. et al.	"The MacIntosh Tibial Plateau Hemiprosthesis for the Rheumatoid Knee", J. Bone Joint Surg. Br. 1972 May: 54 (2): pgs. 256-262.
	CJ	Porter, M.L. et al.	"MacIntosh Arthroplasty: a long-term review", J. R. Coll. Surg. Edinb. 1988 Jan-Feb: (192): pgs. 199-201.
	CK		International Search Report dated 13 May 2005.

Examiner Signature: \_\_\_\_\_

Date Considered: \_\_\_\_\_

EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; draw line through citation *if not* in conformance and not considered. Include copy of this form with next communication to applicant.

**Section 6. Copies of Listed Information Items Accompanying This Statement**

*NOTE: 37 C.F.R. section 1.98(a)(2) requires that any information disclosure statement filed under section 1.97 shall include: "A legible copy of: (i) Each U.S. and foreign patent; (ii) Each publication or that portion which caused it to be listed; and (iii) All other information or that portion which caused it to be listed, except that no copy of a U.S. patent application need be included . . ."*

*NOTE: The wording in section 1.98(a)(2)(iii) makes it clear that the requirement to submit a copy of each item of information listed in an information disclosure statement does not apply to the citation of a U.S. patent application. Notice of January 9, 1992, 1135 O.G. 13-25, at 14.*

Legible copies of all items listed in Forms PTO/SB/08A and 08B (substitute for Form PTO-1449) accompany this information statement.

*(complete the following, if applicable)*

☒ Exception(s) to above:

☐ Items in prior application, from which an earlier filing date is claimed for this application, as identified in Section 4.

☐ Cumulative patents or publications identified in Section 5.

**U.S. patent citations are not included pursuant to the United State Patent and Trademarks Office's September 21, 2004 waiver of the copy requirement in 37 CFR 1.98 for cited pending U.S. patent citations when the patent citations are available in the USPTO's IFW system.**

**Section 7A. Concise Explanation of Non-English Language Listed Information Items—EPO Search Report**

The relevance with respect to the following citations listed on Forms PTO/SB/08A and 08B (substitute for PTO-1449):

is submitted on the basis of the accompanying:

*(check the appropriate item)*

☒ EPO search report that is in the English language,

☐ EPO search report that is not in the English language and that is accompanied also by an English language version of the EPO search report,

that issued on the corresponding European patent application.

**Section 10. Identification of Person(s) Making This Information Disclosure Statement**

The person making this certification is

*(check each applicable item)*

- (a) ☐ the inventor(s) who signs below

\_\_\_\_\_  
**SIGNATURE OF INVENTOR**

\_\_\_\_\_  
*(type name of inventor who is signing)*

- (b) ☐ an individual associated with the filing and prosecution of this application (37 C.F.R. section 1.56(c))

\_\_\_\_\_  
**SIGNATURE OF INVENTOR**

\_\_\_\_\_  
*(type name of inventor who is signing)*

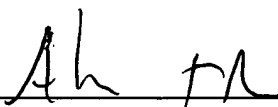
- (c) ☒ the practitioner who signs below on the basis of the information:

*(check each applicable item)*

☐ supplied by the inventor(s).

☐ supplied by an individual associated with the filing and prosecution of this application. (37 C.F.R. section 1.56(c)).

☒ in the practitioner's file.

  
\_\_\_\_\_  
**SIGNATURE OF PRACTITIONER**

Alexander J. Smolenski, Jr., Esq.

*(type or print name of practitioner)*

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2960/118 395490